NRC Commissioners Briefing: Implementation of Energy Policy Act of 2005

Sally W. Schwarz, M.S., B.C.N.P.
Nuclear Pharmacy Representative,
Advisory Committee Medical Use of Isotopes (ACMUI)

May 15, 2006

Acronyms Used in Presentation

- PET: Positron Emission Tomography
- FDG: Fluorine-18 fludeoxyglucose
- $NH_{3:}$ N-13 ammonia
- Rb: Rubidium-82 Chloride
- IMV: Information Means Value—Research Marketing Analysis
- FLT: Fluorine-18 flurothymidine
- FMISO Fluorine-18 fluoromisonidazole
- Cu-ATSM: Copper-64 diacetyl-bis-methylthiosemicarbazone

Acronyms Used in Presentation

- F-RGD: Fluorine-18 cyclo(-Arg-Gly-Asp-D-Phe-Lys-(sugar amino acid)-)
- FDOPA: Fluorine-18 fluorodopa
- PIB: Carbon-11 Pittsburgh compound B
- F-Amyloid: Fluorine-18 amyloid
- ACMUI: Advisory Committee Medical Use of Isotopes
- T&E: training and experience
- NARM: Naturally occurring or Accelerator produced Radioactive Material

Acronyms Used in Presentation

- CT/PET: Computed tomography/PET
- R&D: Research and development
- RAM: Radioactive Materials
- FDOPA: Fluorine-18 fluorodopa
- FDA: Food and Drug Administration
- IAEA: International Atomic Energy Agency

Importance of PET

- PET is an integral part of clinical Nuclear Medicine—field rapidly advancing the diagnosis and treatment of the most prevalent diseases:
  - Cancer: >90% of all studies-FDG
  - Cardiovascular Disorders:

    Perfusion; NH_3, Rb; Viability; FDG
  - Brain disorders (dementia, seizures)-FDG

PET Statistics

- Number of Cyclotrons USA: 2005: 177; 2006: 185
- Number of PET scanners USA: 2005: 1280
- Number of PET scans performed
  - 2000: 211,600
  - 2005: 1,180,625
  - 2010 (projected): 2,086,647

  Data from IMV Research

Current PET Advances

- Research and Development
  - Cancer diagnosis: proliferation: FLT; hypoxia: FMISO, Cu-ATSM; Monitoring anti-angiogenesis: F-RGD
  - Neurological Disorders, Alzheimer's (FDOPA, PIB, F-Amyloid)
  - Cardiovascular Perfusion/Viability (F-18 flow agent)
  - Monitoring Therapy
- CT/PET

Accelerator-produced Radioactive Material

- ACMUI supports proposed categorization of accelerators
- ACMUI endorses Not regulating therapy accelerators
- ACMUI supports High compatibility across state lines for
  - Mobile PET licenses
  - Centralized nuclear pharmacies
  - Standardized T&E requirements

ACMUI Concerns

- Maintaining availability of PET radiopharmaceuticals for research & clinical practice is essential
- Noncommercial distribution of PET radionuclides for R&D
- Impact of Decommissioning Financial Assurance
  - Creates special hardship for older facilities
  - Concerns regarding 16 MeV cyclotrons

ACMUI Concerns (continued)

- Aggressive implementation schedule may be difficult for new NARM licensees and NRC
  - mobile PET, free standing PET facilities
- License guidance needed at publication date of the final rule, which has been vetted
  - ACMUI must review prior to publication to refine and clarify

ACMUI Comments

- NRC moving all RAM under single umbrella, similar to State regulation for ~40 years
- Must allow sufficient time interval for all states to come into compliance
- FDA has been “in process” of establishing regulations for FDG since 1995
- Medicare: May 8, 2006 extended coverage to cover all cancers under the new PET registry

Ra-226 Discrete Sources

- Obsolete for medical/clinical applications since ~1989
- No other discrete sources (similar to Ra-226) expected for medical or medical research use
- Number of Ra-226 sources remaining in inventory is unknown
  - But << IAEA Code of Conduct Category 2 sources